# ADVANCED ANTACID REGULAR STRENGTH- aluminum hydroxide, magnesium hydroxide, dimethicone liquid

#### STRATEGIC SOURCING SERVICES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### SUNMARK ANTACID ORIGINAL

### Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200mg (equivalent to dried gel, USP) Magnesium hydroxide 200 mg Simethicone 20mg

#### **Purposes**

Antacid

Antigas

#### Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

#### **Warnings**

#### Ask a doctor before use if you have

- · kidney disease
- a magnesium-restricted diet

#### Ask a doctor or pharmacist before use if you are taking a

prescription drug. Antacids may interact with certain prescription drugs.

**Stop use and ask a doctor if** symptoms last more than 2 weeks

**If pregnant or breast-feeding,** ask a health professional before use.

Keep out of reach of children.

#### **Directions**

- shake well before use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not take more than 24 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
- children under under 12 years: ask a doctor

#### Other information

- each 5 mL teas poonful contains: magnesium 85 mg, sodium 1 mg
- protect from freezing
- store at room temperature
- keep tightly closed

## **Inactive ingredients**

benzyl alcohol, butylparaben, flavor (contains alcohol), hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

## package label

Sunmark

compare to active ingredients of the Regular Strength Mylanta®\*

NDC 49348-153-39

advanced

antacid

Regular Strength

antacid/antigas

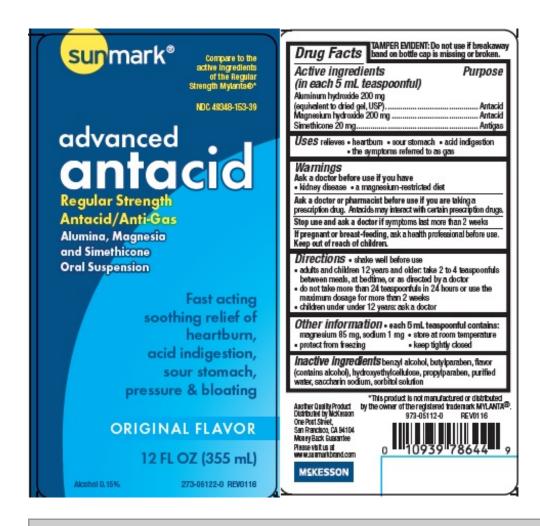
Alumina, Magnesia and Simethicone Oral Suspension

Fast acting soothing relief of heartburn, acid indigestion, sour stomach, pressure & bloating

ORIGINAL FLAVOR

Alcohol 0.15%

12 FL OZ (355 mL)



#### ADVANCED ANTACID REGULAR STRENGTH

aluminum hydroxide, magnesium hydroxide, dimethicone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-153
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL		
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL		
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL		

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)		

PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		

	Packaging				
	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
	1 N	DC:49348-153-39	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2012	
П					

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/01/2012	

# Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

# **Registrant -** GCP Laboratories (965480861)

Establishment				
Name	Address	ID/FEI	Business Operations	
GCP Laboratories		965480861	manufacture(49348-153)	

Revised: 12/2019 STRATEGIC SOURCING SERVICES LLC